

### **REMARKS**

Claims 73-91 and 94-100 were pending in the present application. By this Amendment, Applicants have canceled claims 95-98 without prejudice to the right to present the canceled subject matter in a future continuing application. The present Amendment does not introduce any new matter, and thus, its entry is respectfully requested. Upon entry of the present Amendment, claims 73-91, 94, and 99-100 will remain pending and under examination.

#### **August 1, 2006 Office Action**

##### **Examiner's Claim Rejections Under 35 U.S.C. § 112**

Claims 73-91 and 94-100 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. According to the Examiner, the claim language “wherein said contacting occurs without a prior washing step following the negative test”, as presented in the previously filed Amendment, represents new matter, which does not find adequate support in the specification. In rejecting the claims, the Examiner first asserted that the portions of the specification that Applicants previously pointed to as providing support for the absence of the washing step are silent as to the use of such a step and that such silence does not equate to a description adequately supporting the absence of such a wash step in the claimed method. The Examiner also asserted that the specification, which states at page 25, lines 24-26, “[a]fter washing and drying the said crystal, resonant frequency values were determined”, contradicts Applicants’ position that the claims are fully supported by the application as

originally filed. Accordingly, the Examiner has taken the position that the claims, as presented, contain new matter and thus fail to meet the written description requirements under 35 U.S.C. §112, first paragraph.

In response, Applicants respectfully traverse the Examiner's rejection. Applicants maintain that the claims as presented are fully supported by the application as filed. In that regard, Applicants first note that the "washing" step to which the Examiner refers does not take place after the result is obtained, but rather before. In Applicants' view, nothing in the specification contradicts Applicants' claim limitation relating to the absence of a washing step after a negative result and before the reuse of the crystal. With respect to the absence of direct language supporting the claim limitation, Applicants do not dispute that the specification does not provide a statement literally describing this washing step omission. Such literal language is not, however, required for a claim to have adequate written support under section 112. The language to which Applicants previously directed the Examiner's attention in the specification (at page 28), does indeed discuss the re-use of "Crystal 1" for a second test immediately following incubation with the negative serum (which constitutes a first negative test). There is no suggestion of an intervening wash step and the general nature of this particular disclosure suggests none would be necessary. This, in the Applicants' view, represents an example fully supportive of the language recited in the claims. Applicants contrast this with the disclosure at the bottom of the same page, which relates to regeneration of a crystal after a *positive result*, which does describe a wash step before the crystal can be used again. In light of these

disclosures, Applicants maintain that the claims as presented are sufficiently described and supported by the original disclosure and thus Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Examiner's Claim Rejections Under 35 U.S.C. § 103

Claims 73-91 and 94-100 had been previously rejected under 35 U.S.C. §103(a) as being unpatentable over various combinations of the teachings of Bastiaans, et al., LaRue, Thorns, U.S. Pat. 5,306,644, Rajashekara, Willner I and II, Masten, and Protein Accession No. CAA78777. In the August 1, 2006 Office Action, the Examiner withdrew the prior art rejections of the method claims in light of Applicants' submission of the Declaration of Yap Him-Hoo. However, the Examiner maintained rejections of claims 95-98, directed to kits, as obvious in view of the prior art of record. The Examiner's position is essentially that, notwithstanding the recited statements of intended use, these claims are not method claims, and thus, the feature that distinguishes the method claims over the art, i.e., the absence of the wash step, is not relevant.

In response, Applicants acknowledge and appreciate the withdrawal of the previous prior art rejections of the method claims. With respect to the rejection of claims 95-98, without conceding the correctness of the Examiner's position, but to expedite allowance of the application, Applicants have canceled claims 95-98 without prejudice. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections set forth under 35 U.S.C. §103(a).

Upon cancellation of claims 95-98, only claims deemed to be free of the prior art remain

in the application.

In view of the above remarks and claim cancellations, Applicants believe that the Examiner's rejections set forth in the August 1, 2006 Office Action have been fully addressed and that the present claims fully satisfy the patent statutes. Applicants therefore believe that the application is in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

No fee is believed due in connection with the filing of this Amendment. If, however, any fee is necessary, authorization is hereby given to charge such fee, or credit any overpayment, to deposit Account No. 02-2135.

Respectfully submitted,

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By:



Patrick T. Skacel  
Registration No. 47,948  
Attorney for Applicants  
Rothwell, Figg, Ernst & Manbeck, P.C.  
1425 K Street, N.W., Suite 800  
Washington, DC 20005  
Telephone: (202) 783-6040  
Fax: (202) 783-6031

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